

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Stephen M. Kelsey et al.  Serial No.: 10/608,626  Filed: June 27, 2003	Group Art Unit: 1643  Examiner: Hong Sang  Confirmation No: 4813  CUSTOMER NO: 09157
For: Treatment with Anti-ErbB2 Antibodies	<p style="text-align: center;"><b>Electronically Filed On:</b></p> <p style="text-align: center;"><b>August 29, 2006</b></p>

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☒ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set

forth in 37 CFR § 1.17(p) or a statement as specified in 37 CFR § 1.97(e), as checked below.

☐ **37 CFR § 1.97(d)**

- after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) and a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

☐ **37 CFR § 1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ **37 CFR § 1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.

☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449.

Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (\*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR § 1.98(a)(2)(ii)]. See Final Rule **1287 OG** (October 12, 2004). Other documents cited with an asterisk have not been supplied because they were previously cited by or submitted to the Office in prior application Serial No. 10/268,501, filed October 10, 2002 and benefit from the prior application is claimed in this application under 35 U.S.C § 120. However, copies of any cited document will be provided in its entirety at the request of the Office.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,  
GENENTECH, INC.

Date: August 29, 2006

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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1467R2P2

Serial No.

10/608,626

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Kelsey et al.

Filing Date

27 Jun 2003

Group

1643

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	*354	2003/0086924A1	08.05.03	Sliwkowski, M.			
	*355	2004/0013667A1	22.01.04	Kelsey et al.			
	*356	2005/0208043A1	22.09.05	Adams et al.			
	*357	2005/0238640A1	27.10.05	Sliwkowski, M.			
	*358	2006/0034842A1	16.02.06	Adams et al.			
	*359	2006/0073143A1	06.04.06	Adams et al.			
	*360	2006/0083739A1	20.04.06	Sliwkowski, M.			
	*361	6,949,245B1	27.09.05	Sliwkowski, M.			
	*362	7,041,292B1	09.05.06	Sliwkowski, M.			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	363	Agus et al., "A potential role for activated HER-2 in prostate cancer" <u>Seminars in Oncology</u> 27(6 Suppl 11):76-83 (Dec 2000)
	364	Agus et al., "Clinical Activity in a Phase I Trial of HER-2-Targeted rhuMab 2C4 (pertuzumab) in Patients with Advanced Solid Malignancies (AST)" <u>Proceedings of the American Association for Cancer Research</u> (Abstract No. 771) 22:192 (2003)
	365	Agus et al., "Clinical Activity in a Phase I Trial of HER2-Targeted rhuMab 2C4 (pertuzumab) in Patients with Advanced Solid Malignancies" (Slides presented at the 2003 ASCO Annual Meeting) pps. 1-32 (2003)
	366	Gilbertson, R.J., "Expression of ErbB-Neuregulin Signaling Network during Human Cerebellar Development: Implications for the Biology of Medulloblastoma" <u>Cancer Research</u> 58:3932-3941 (Sep 1, 1998)
	367	Gilbertson, R.J., "Prognostic Significance of HER2 and HER4 Coexpression in Childhood Medulloblastoma" <u>Cancer Research</u> 57:3272-3280 (Aug 1, 1997)
	368	Gilbertson, R.J., "The ErbB2 receptor represents a potential target for novel therapies in childhood medulloblastoma" <u>Clinical Cancer Research</u> (Abstract #38) 5(Suppl.):3737s (Nov 1999)
	369	Gordon et al., "Clinical activity of pertuzumab (rhuMab 2C4) in advanced, refractory or recurrent ovarian cancer (OC), and the role of HER2 activation status" <u>Journal of Clinical Oncology</u> (Abstract #5051 from the 41st Annual Meeting of ASCO) 23(16S):467s (Jun 1, 2005)
	370	Gordon et al., "Clinical activity of pertuzumab (rhuMab 2C4) in advanced, refractory or recurrent ovarian cancer and the role of HER2 activation status" (Poster #5051 from the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO)) (May 15, 2005)
	371	Grossi, P.M., "Efficacy of Intracerebral Microinfusion of Trastuzumab in an Athymic Rat Model of Intracerebral Metastatic Breast Cancer" <u>Clinical Cancer Research</u> 9:5514-5520 (Nov 15, 2003)

Examiner	Date Considered
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.